TRACC
Global Research & Consulting Pvt Ltd
CDSCO MANUFACTURING LICENSE FOR MEDICAL DEVICES
End-to-End Regulatory Support for Medical Devices & Healthcare Products
OUR CORE SERVICES
Regulatory Services (MDR 2017 Compliance, CDSCO Registration)
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Global Device Registration (India, USA, UK, Vietnam, etc.)
WHO PQ Compliance Support
Regulatory Training & Consultancy
KEY BENEFITS
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Global Compliance Expertise
Complete Documentation Support
Hassle-Free Approval Process
GLOBAL REACH India, USA, UK, Vietnam & More
100% Regulatory Compliance
END-TO-END Regulatory & Documentation Support
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FDA REGISTERED CONSULTANT
CDSCO

CDSCO Manufacturing License for Medical Devices The CDSCO Manufacturing License for Medical Devices is a crucial regulatory approval required for businesses engaged in the production of medical devices in India. CDSCO (Central Drugs Standard Control Organization), under the Ministry of Health and Family Welfare, ensures that all medical devices meet strict safety, quality, and performance standards before they reach the market. With the implementation of Medical Device Rules, 2017, it has become mandatory for manufacturers to obtain a valid CDSCO manufacturing license before starting operations. This regulation helps maintain consistency, patient safety, and product reliability across the healthcare industry. Medical devices in India are classified into four categories based on their risk level: Class A – Low Risk (e.g., surgical dressings) Class B – Low to Moderate Risk (e.g., hypodermic needles) Class C – Moderate to High Risk (e.g., infusion pumps) Class D – High Risk (e.g., cardiac stents) Each class has specific compliance and approval requirements, and the licensing process varies accordingly. Eligibility Criteria: Any individual, company, or organization involved in manufacturing medical devices must apply for a CDSCO Manufacturing License. The applicant must have: - A properly established manufacturing facility - Qualified and experienced technical staff - Quality management systems in place (ISO 13485 recommended) Documents Required: - Application forms (MD-3, MD-7, etc.) - Plant Master File (PMF) - Device Master File (DMF) - ISO 13485 Certificate - Details of manufacturing process - Site layout plan - Technical staff qualification documents Application Process: 1. Register on the CDSCO online portal 2. Submit application with required documents 3. Pay applicable government fees 4. CDSCO inspection of manufacturing site 5. Approval and license issuance Benefits of CDSCO Manufacturing License: - Legal authorization to manufacture medical devices - Enhanced credibility and trust in the market - Compliance with Indian regulatory standards - Opportunity to expand into global markets - Better quality assurance and risk management Validity: The CDSCO Manufacturing License remains valid indefinitely unless suspended or canceled, subject to regular compliance and audits. Why Choose TRACC Global Research And Consulting Pvt Ltd? TRACC Global offers expert consultancy services for obtaining CDSCO Manufacturing Licenses. With a team of experienced regulatory professionals, we provide complete end-to-end support including documentation, submission, compliance, and approval. Visit our website for more Information: https://traccglobal.com/cdsco-manufacturing-license/ Call us:- +918868886774 Address: TRACC Global Research And Consulting Pvt Ltd, 1271, Ground Floor, Sector-45, Gurugram, Haryana-122001.